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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,712	10/09/2001	Antonio Basetta	02508.0089	8628

7590 01/23/2004

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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/899,712

Applicant(s)

BOSETTO ET AL.

Examiner

John Kim

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 18-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-31 and 33-40 is/are allowed.
- 6) ☒ Claim(s) 1-4, 18-25 and 41-43 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

1. Claim 32 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 32 should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 32 has not been further treated on the merits.
2. Claims 1-4, 18-19 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,616,248 (hereinafter referred to as Schal). Schal teaches method for preparing dialysis fluid comprising circulating water in a preparation circuit (4) at a flow rate, injecting into the preparation conduit (16a) at a flow rate a first concentrated solution (14a) comprising sodium and potassium at first concentration, injecting into the preparation conduit (5) at a flow rate a second basic concentrated solution containing sodium and regulating the injection flow rates of first and second concentration via pumps (15a) to form dialysis fluid of desired concentration of sodium and potassium wherein the flow rates are varied to vary the concentration of sodium or potassium over the course of time wherein potassium concentration decreases from 4 to 1 mmol/l or holding the sum of flow rates constant by a fixed ratio such that concentration of sodium is held constant (see figure 6; col. 7, lines 8-12, 26-29; col. 8, lines 1-9, col. 9, line 15 – col. 10, line 49; col. 13, lines 45-52, col. 14, line 3 – col. 16, line 15).
3. Claims 20-25 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,616,248 (hereinafter referred to as Schal). Schal teaches method for preparing dialysis fluid comprising circulating water in a preparation circuit (4) at a flow rate, injecting into the preparation conduit (5) at a flow rate a concentrated solution containing sodium and injecting into the preparation conduit (16a) at a flow rate a first concentrated solution (14a) of sodium and potassium at first concentration and injecting into the conduit (16b) a second concentrated solution (14c2) of sodium and potassium at second concentration different than the first

concentration and regulating the injection flow rates of first and second concentration via pumps (15c1, 15c2) to form dialysis fluid of desired concentration of sodium and potassium wherein the flow rates are varied to vary the concentration of sodium or potassium over the course of time wherein potassium concentration decreases from 4 to 1 mmol/l or holding the sum of flow rates constant such that concentration of sodium is held constant (see figure 6; col. 15, line 1 – col. 6, line 15). Claims 20-25 and 41 essentially differ from the method and solutions of Schal in reciting that the two concentration solutions being identical to each other except that the concentration of the second ionic substance B differs from the one solution to the other. Schal teaches that profiling of sodium and potassium is varied by regulating the flow of two different individual concentrates (see col. 15, line 26 – col. 16, line 15). Individual concentrates are used to supplement sodium, potassium, calcium and magnesium and also glucose in various concentration range to the basic dialysis fluid to its final composition of dialysis fluid, individually adapted to the patient (see col. 6, lines 38-53; col. 15, lines 1-13). Providing two individual concentrates having only different concentration of second ionic substance such as potassium would have been obvious to a person of ordinary skill in the art at the time the invention was made to make up the final composition of dialysis fluid individually adapted to the patient.

4. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/08299 (hereinafter referred to as WO '299) in view of Schal. WO '299 teaches a liquid mixing assembly for mixing at least two liquids including a container divided into two separate compartments (4a, 4b) in side-by-side relation wherein each compartment contains one of dialysis liquids (see abstract; figure 1). Schal teaches dialysis fluid preparing concentrates

comprising a first concentrated solution (14c1) of sodium and potassium at first concentration and a second concentrated solution (14c2) of sodium and potassium at second concentration different than the first concentration and basic concentrate having zero potassium concentration (see col. 8, lines 1-9, col. 15, line 51 – col. 16, line 15). It would have been obvious to a person of ordinary skill in the art to contain two concentrates of Schal in the each compartment of the container of WO '299 for facilitating the process of mixing and preparing desired dialysis fluid.

5. Claims 26-31 and 33-40 are allowed.
6. Applicant's arguments with respect to claims 1-4 and 18-43 have been considered but are moot in view of the new ground(s) of rejection.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,244,568 and 5,567,320 and 5,346,472 and 4,923,613 and 5,578,223 and 6,635,026 teach dialysis fluid preparation method.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT", otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
January 9, 2004